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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,607

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Xavier Paliard

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NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,607	Applicant(s) PALIARD ET AL.	
	Examiner Bao Qun Li	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-65 is/are pending in the application.
- 4a) Of the above claim(s) 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-48 and 63-65 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The response filed on Feb. 11, 2008 has been acknowledged. Claims 45-65 are pending. Claims 49-62 were withdrawn from consideration. Claims 45-48 and 63-65 are considered before the examiner.

Priority

The priority based on the effective filing date of the provisional Application No. 60,161,713 is still denied. In the response, Applicants do not assert the objection. Moreover, Applicants have submitted a Declaration under Rule 1.131 demonstrating that Applicants had possession of construct of polynucleotide encoding fusion protein containing NS3, NS4 and NS5 polypeptides, which does not contain the core antigen of HCV prior to March 1999.

Declaration under 37 CFR 1.131

The Declaration filed on Feb. 11, 2008 under 37 CFR 1.131 is sufficient to overcome the 103 (a) reference by Cho et al. (Vaccine, March 1999, Vol. 17, pp. 1136-1144).

The rejection of claims 45-49 and 63-65 under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (Vaccine 1999, Vol. 17, pp. 1136-1144) and Lagging et al. (J. Virol. 1995, Vol. 69, No. 9, pp. 5859-5863) or Geissler et al. (J. Immunol. 1997, Vol. 159, pp. 5107-5113) has been removed.

Claim Rejections - 35 USC §103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 45-48 and 63-65 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (a) (US patent No. 5,683,864A1, "864" patent) or Houghton et al. (b) (US patent No. 6,312,889B1, "889" patent).

3. Applicants traverse the rejection and submit that Examiner failed to establish a prima facie case of obviousness for the following reasons:

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4. a). Houghton et al. in “864”, “889” and “771) pertain to immunoassays using polypeptide antigens for detection of antibodies in sera, rather than an immunization with HCV polynucleotide and similarly the claimed composition lacks an adjuvant.

5. b). The NS3 described in the references derived from residues 1050-1640, whereas the claimed polypeptide is the full length NS3 with amino acid residues 1027-1657.

6. Applicants’ response has been fully considered; however, it is not found persuasive to withdraw the rejection for all pending claims. In particular, claims 45-48 and 63 are not directed to an immunogenic composition comprising an adjuvant. They are just directed to an isolated and purified polynucleotide as plasmid DNA. Houghton et al. in both (a) and (b) teach a polynucleotide encoding a fusion protein comprising the HCV antigen polyprotein of NS3, NS4, NS5 and Core, i.e. N’-NS3/NS4/NS5/Core -C’ or the entire amino acid sequence of the HCV (See column 5 in US patent “889B1” or “864”), while an option of NS3 polypeptides contains amino acid residues from 1050-1064, but it is not limited to that fragment. In fact, claim 1 describes that the NS3 that includes the amino acid residues from 1054 to 1640, and the NS4 includes the polypeptide right after the amino acid residue 1640 till the amino acid residue 2000. To this context, it covers the amino acids from 1640 till 1657 as claim 45 drafted. An adjuvant addition in an immunogenic composition is well known and commonly used by an ordinary skilled in the art to obtain more effective immune response.

7. Therefore, a skilled artisan would have been motivated to make a polynucleotide construct that encodes the fusion proteins comprising full length HCV NS3 fused with other non-structural proteins of NS4, NS5a and NS5b and structural protein Core antigen in combination with an adjuvant to induce more significant immune response in a subject absence of any unexpected result. Because the construct encoding NS345ab and Core are approved to be able to express the immunogenic polypeptide for each of the structural and non-structural proteins when it is used for transforming a host cell regardless it can be used for diagnosis or immunization. The purpose for using an immunogenic composition differently is considered to be obvious for a person ordinarily skilled in the art. Regarding this rejection, Applicants are further referred to the case law about *KSR International Co. v. Teleflex Inc.*

8. *The case law about KSR International Co. v. Teleflex Inc.*— conclude that Ordinary Innovation is obvious. In *KSR*, the Supreme Court did not entirely reject the “teaching,

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suggestion, or motivation” test, but rather criticized the formalistic and rigid application of this test by the Federal Circuit in this case. The Court acknowledged that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art. But, the Court ruled that any teaching, suggestion or motivation does not need to be explicit and courts can take into account the inferences and creative steps that a person of ordinary skill in the art may employ: “A person of ordinary skill is also a person of *ordinary creativity*, not an automaton.” In order to determine whether there was a reason for one skilled in the art to combine known elements in a manner claimed by the patent, courts must analyze the interrelated teachings of prior art references, the effects of known demands in the marketplace, and the background knowledge possessed by a person of ordinary skill in the art. The Supreme Court stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results, and further indicated that any of the following may provide a “reason” for combining these known elements: a need or problem known in the field of endeavor at the time of invention and addressed by the patent; an obvious use of familiar elements beyond their primary purposes; or a design need or market pressure to solve a problem (Morrow et al. *The case law about KSR International Co. v. Teleflex Inc.*— conclude that Ordinary Innovation is Obvious, published in the internet website: www.fewick.com, 2007, pages 1-2).

9. Therefore, suggestion or motivation does not need to be explicit and courts can take into account the inferences and creative steps that a person of ordinary skill in the art may employ. “A person of ordinary skill is also a person of *ordinary creativity*, not an automaton.”

Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

10. Hence, absence of an unexpected result to the contrary, the claimed invention as a whole is prima facie obvious absent unexpected results.

11. The rejection of claims 45-48 and 63-65 under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (c) (WO 91/15771) has been removed in view of the argument described above, because Houghton et al. (c) do not contain the disclosure of a polynucleotide encoding a fusion protein comprising the HCV antigen polyprotein of NS3, NS4, NS5 and Core (N'-NS3/NS4/NS5/Core -C') or the entire amino acid sequence of the HCV.

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Conclusion

No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

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/Bruce Campell/

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Supervisory Patent Examiner, Art Unit 1648